

ATTORNEY DOCKET NO. 02-061 (ANSI01-00009)
U.S. SERIAL NO. 09/670,062
PATENT

REMARKS

Claims 1, 2, 4-10, 12-17, 30 and 32 are pending in the application.

Claims 1, 2, 4-10, 12-17, 30 and 32 have been rejected.

I. OBJECTION TO THE SPECIFICATION

The Examiner has objected to the specification stating that "preferably" should be deleted from the paragraph amended in the prior amendment. Applicant has deleted "preferably" as suggested by the Examiner. Applicant requests the Examiner to withdraw the objection.

II. REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 1-8, 9-17, 30 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,280,511 (hereinafter referred to as "O'Neill") in view of U.S. Patent No. 4,934,049 (hereinafter referred to as "Kiekhafer") in view of U.S. Patent No. 5,417,208 (hereinafter referred to as "Winkler").

Claims 1-8, 30, and 32 are cancelled without prejudice and, hence, the rejection of these claims is not addressed herein.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the applied reference

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(or references when combined) must teach or suggest all the claim limitations. *See* MPEP § 2143.

Applicant respectfully submits that the applied references do not satisfy these criteria.

Claim 9 recites:

a lead body having an insulator and multiple conductors, wherein the insulator includes a respective welding region for each of said multiple conductors formed by removal of at least a portion of the insulator, each welding region formed to expose at least a portion of a respective conductor, wherein each welding region is formed obliquely across said lead body and parallel to a respective conductor;

a respective elongated conductive element, for each welding region, having a distal end and a proximal end, the proximal end electrically connected to the conductor within the corresponding welding region; and

a respective band welded to the distal end of each elongated conductive element to electrically connect the band to the respective conductor, the band welded to the distal end of the elongated conductive link element outside of the welding region.

Elongated Conductive Element

Applicant respectfully submits that none of the applied references teaches or suggests an elongated conductive element as claimed. For the convenience of the Examiner, Applicant notes that an example of an elongated conductive element is shown as element 34 in Figures 4 and 5 of the present application. Also, Applicant is unable to identify from the Office Action which structure in which applied reference is asserted to meet the "elongated conductive element" limitation of claim 9. Accordingly, Applicant addresses the pertinent structures of each reference below.

O'Neill merely discloses a "bipolar" pacing lead having ring electrode 10 and tip electrode 22 having multiple "tines." Col. 2, lines 55-61; *See* Figures 1-3. As explicitly disclosed by O'Neill, ring electrode 10 is electrically coupled to conductor 14 through soft metal 18. Col. 3, lines 31-38.

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A reasonable interpretation of an "elongated conductive element...having a distal end and a proximal element" is simply not consistent with soft metal 18 of O'Neill. Also, soft metal 18 is not welded at a proximal end within a welding region to a conductor of the lead. Soft metal 18 also does not have a distal end welded to a ring conductor outside of the welding region. In regard to the tines of tip electrode 22, the tines could be considered "elongated." However, the tines of tip electrode 22 are not welded at a proximal end within a welding region to a conductor of the lead. Also, the tines of tip electrode 22 are not welded to a band at a distal end and outside of the "welding region."

Kiekhafer merely discloses a lead in which an outer "electrode coil 12" is coupled to a inner coil 36 of the lead body. Col. 2, lines 31-49 and Figure 2. Because Kiekhafer merely discloses two mutually adjacent coils, there is simply no "elongated conductive element" in Kiekhafer as recited in claim 9.

Winkler merely discloses creating a band electrode by wrapping a flat conductive element 51 around a medical lead according to an exposed window 47 in the insulative material of the lead. The excess portion of the conductive element 51 is trimmed and the ends of conductive element 51 are welded together thereby forming a loop. Col. 6, lines 51-67; see Figures 4C and 4D. By being coupled to one of the inner wound wires 45, this loop forms the ring electrode 30. Thus, element 51 of Winkler does not meet the "elongated conductive element" of claim 9. Specifically, element 51 of Winkler does not have a distal end or a proximal end, since the final form of element 51 is a continuous loop. Moreover, there is no distal end of element 51 of Winkler that is coupled to a separate "band," because element 51 itself is a band electrode. Also, as recited in claim 9, the distal

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end of the elongated conductive element must be welded to the band outside of the "welding region" in which the elongated conductive element is coupled to a conductor of the lead. There is no such teaching or suggestion in Winkler.

Thus, the applied references (either alone or in combination) do not teach or suggest each and every limitation of claim 9. Accordingly, Applicant submits that a prima facie case of obviousness has not been established for claim 9. Claims 10 and 12-17 depend from claim 9 and, hence, a prima facie case of obviousness has not been established for these claims.

Orientation of the Welding Region

Claim 9 also recites that "each welding region is formed obliquely across said lead body and parallel to a respective conductor."

In regard to claim 9, none of the applied references disclose an orientation for the welding region in the manner recited by claim 9. Instead, the Office Action states that the present application does not disclose any criticality to the orientation of the welding region and, therefore, the orientation of the welding region is treated as an obvious design choice.

Applicant respectfully submits that such a rejection cannot be maintained as a matter of law. Specifically, Applicant is only required to provide a written description of the invention to enable one of ordinary skill in the art to make and use the invention. Once Applicant has satisfied this requirement, the burden is shifted to the Patent Office to demonstrate a factual basis for the unpatentability of the invention. See *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976);

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In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); *In re Saunders*, 444 F.2d 599, 170 USPQ 213 (CCPA 1971); *In re Tiffin*, 443 F.2d 394, 170 USPQ 88 (CCPA 1971), *amended*, 448 F.2d 791, 171 USPQ 294 (CCPA 1971); *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). If a factual basis in the prior art is not shown (i.e., the claimed structures are not found), Applicant is entitled to a patent on the claimed invention.

Accordingly, because the applied references unquestionably do not teach or suggest the recited orientation of the welding region, Applicant submits that claim 9 is patentable over the applied references. Claims 10 and 12-17 depend from claim 9 and, hence, are also patentable.

III. CONCLUSION

As a result of the foregoing, the Applicant asserts that the remaining Claims in the Application are in condition for allowance, and respectfully requests an early allowance of such Claims.

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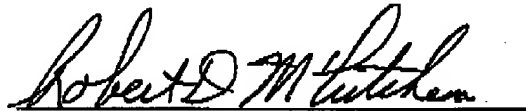
If any issues arise, or if the Examiner has any suggestions for expediting allowance of this Application, the Applicant respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at rmccutcheon@davismunck.com.

The Commissioner is hereby authorized to charge any additional fees connected with this communication or credit any overpayment to Davis Munck Deposit Account No. 50-0208.

Respectfully submitted,

DAVIS MUNCK, P.C.

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Robert D. McCutcheon
Registration No. 38,717

P.O. Box 802432
Dallas, Texas 75380
(972) 628-3632 (direct dial)
(972) 628-3600 (main number)
(972) 628-3616 (fax)
E-mail: rmccutcheon@davismunck.com